

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant : Matthias Ebert et al.

Serial No.: 10/575,300

Group Art Unit: 1642

Filed : September 18, 2006

Examiner: Sean E. Aeder

For : MN and Cancer Prognosis

INTERVIEW SUMMARY

MAIL STOP AMENDMENT

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

Sir:

The following is a Statement of Substance of a telephone interview conducted between Examiner Sean Aeder and Attorney and Agent for Applicants on April 29, 2008, concerning the above-identified application.

STATEMENT OF SUBSTANCE  
OF APRIL 29 INTERVIEW

Applicants gratefully acknowledge the telephone interview granted by Examiner Sean Aeder on April 29, 2008 to the undersigned Attorney for the Applicants and the patent agent with whom she works, Joan Harland, Ph.D. The interview was requested to clarify points presented in Applicants' Request for Continued Examination [RCE] filed on March 26, 2008, in response to the Advisory Action mailed on January 29, 2008. The two 35 USC §112, ¶1 rejections (written description and enablement) maintained in the Advisory Action were discussed at the April 29 interview.

Applicants first asked whether the 35 USC §112, written description rejection was adequately addressed by the amendments to Claim 1 and Claim 24 filed in the RCE, which amendments limited the subject diseases to those of previous Claim 3, which diseases had been shown by Ivanov et al. to lose CA IX expression upon carcinogenesis (as discussed in the RCE at page 18). The Examiner indicated that the amendments to Claims 1 and 24 were sufficient to overcome the 35 USC §112, written description rejection.

In response to Examiner's previous argument that MN/CA IX was not a reliable marker of poor prognosis, as evidenced by the divergent pattern found in renal cell carcinoma [RCC]

patients, Applicants respectfully argued that RCC is the exception to the rule (as well as being unique in that most RCC stems from a VHL gene mutation uncoupling MN/CA IX expression from hypoxia), and that because hypoxia is characteristic of tumors with poor prognosis and MN/CA IX is the most hypoxia-inducible biomarker found to date, MN/CA IX is not any "particular marker" and is predictable enough for enablement of the claimed methods.

As pointed out in the RCE dated March 26, 2008 (at pages 27-41), even in the unclaimed genus of diseases which includes RCC (i.e., those diseases of tissues in which MN/CA IX is not normally expressed, but exhibits an increased expression upon carcinogenesis), MN/CA IX is so reliable a marker of poor prognosis that it is being considered by The Cancer Imaging Program of the National Cancer Institute as a generalized marker of poor prognosis related to hypoxia, including prognoses of survival, risk of recurrence and response to treatment [see Tatum et al., Int J Radiat Bio., 82(10): 699-757 (2006), cited in Applicants' arguments at pages 35-37 of RCE filed March 26, 2008]. Applicants further explained that it was previously unknown whether MN/CA IX expression patterns in preneoplastic/neoplastic tissues, which tissues normally express MN/CA IX but lose expression upon carcinogenesis, could be used for prognosis. The recognition by the Applicants that MN/CA IX

expression can be used for prognosis in those tissues that normally express MN/CA IX, but lose expression upon carcinogenesis, provides a benefit to the public as another option for cancer prognosis, and only relates to the number of diseases now recited in Claims 1 and 24 as amended.

The Examiner asked whether Applicants would be willing to incorporate the substance of Claim 2 ("wherein said normal expression of MN/CA IX protein in said tissue indicates that 40% or more of the cells of said tissue express MN/CA IX protein") within Claim 1, and Applicants said that they would be willing to make such an amendment.

#### Conclusion of Interview

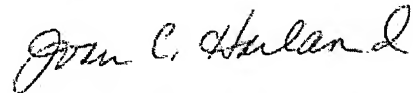
The Examiner said that he would look at the arguments submitted with the response. The Examiner also said that he would determine whether an Examiner's amendment incorporating Claim 2 within Claim 1 would be sufficient to address the instant enablement rejection, which amendment would result in the allowance of the pending claims.

#### CONCLUSION

Applicants respectfully conclude that the pending claims are in condition for allowance, and earnestly request that the claims be promptly allowed. If for any reason the

Examiner feels that a telephone conference would expedite the prosecution of the subject application, the Examiner is invited to telephone the undersigned Agent for Applicants at (415) 981-2034.

Respectfully submitted,

A handwritten signature in cursive script, reading "Joan C. Harland".

Joan C. Harland, Ph.D.  
Agent for Applicants  
Registration No. 51,779

Dated: June 12, 2008